Washington, DC – Today, Congressman Joe Sestak (PA-07) voted for H.R. 2749, the Food Safety Enhancement Act. The bill, which passed the House of Representatives with a bipartisan majority of 283 - 142, gives the Federal Drug Administration (FDA) more authority to recall tainted products, inspect facilities that process food supplies, and establishes food safety guidelines for food processing facilities. The bill, which is a compromise solution crafted by the House Committees on Energy and Commerce and Agriculture, also includes numerous protections for farmers and smaller facilities to guarantee that the implementation of these new regulations will not jeopardize family farms, organic producers, or smaller processors.

"This bill takes essential steps to protecting the health and safety of our nation by establishing the processes needed to secure our food supply and it does so while considering the needs of small business" said Congressman Sestak. "We will prevent food-borne outbreaks, be better prepared to respond to them when they do occur, and establish a process that protects public health while working for businesses and farmers."

This bill overhauls food safety regulations for farms and food processing facilities. It requires more frequent inspections at food facilities, and gives the FDA the authority to impose criminal and civil penalties for violations. The measure establishes new registration requirements and annual fees for food processing facilities, and imposes new record-keeping requirements. In addition, the measure gives the FDA authority to impose mandatory food quarantines. The measure requires annual registration for all food facilities, and gives the FDA authority to assess annual registration fees of $500, adjusted for inflation. Farms would be exempt, in most cases, from the bill's registration requirements, fees, and record-keeping regulations. The measure allows the FDA to provide for additional exemptions at its discretion. The bill does establish new regulations for farming practices with respect to fresh produce; however, the FDA would be required to take into consideration the impact of these standards on small-scale and diversified farms.

Specifically the Bill includes:

Inspections
The bill establishes a risk-based inspection schedule for food facilities, to be implemented within 18 months of the bill's enactment. The bill allows the FDA to modify the process for small food producers where risk of contamination has been minimal. The bill requires domestic food manufacturers to permit a government-designated officer access to all records relating to a food item to determine whether the food is adulterated, misbranded or in violation in some other way.

The FDA would also establish and maintain a corps of inspectors for foreign food facility inspections. The inspections would occur on a three tiered system:
Category 1, 'High-Risk' Facilities which manufacture or process food – including any facility that manufactures or processes raw animal products – will have random inspections at least every six to 18 months.
Category 2, "low-risk facilities," will have random inspections at least every 18 months to three years.
Category 3, General Food Facilities, which the bill defines as facilities that "hold food," will have inspections at least every three to four years.

Quarantines
The bill gives the FDA authority to impose mandatory food quarantines. Currently, food quarantines are carried out on a voluntary basis. The FDA could quarantine areas if the secretary of the Department of Health and Human Services reasonably believes contaminated food is located or or originated in that area and there is credible evidence that the product presents a serious threat to humans or animals. The measure ensures that areas subject to a mandatory quarantine be only as large as necessary to contain an outbreak. This authority includes prohibiting or restricting the movement of food within the area. The bill also establishes reporting requirements for the FDA in the event of a quarantine and requires the FDA to work with state officials.

Traceability Regulations
The bill requires the FDA to establish a tracing system for food located in or imported into the United States. These regulations would apply to those who produce, process, transport, or hold food. Those individuals would be required to maintain the full record of the food. The measure requires the FDA to identify technologies for tracing the history of food as well as the costs and benefits associated with the adoption and use of different technologies and their feasibility for different sectors of the food industry. The measure requires the FDA to consult openly with the public in diverse geographical areas prior to the implementation of these restrictions.

Exemption for Farms
In issuing these regulations, the FDA would be required to coordinate with the Agriculture Department and take into account "the nature of the impact of the regulations on farms." In addition, food would be exempt from the requirements of this if it is produced on a farm and sold by the owner, operator, or agent in charge of the farm directly to a consumer or to a restaurant or grocery store. Any tracing system established with regard to low risk commodities would be significantly limited.

Criminal & Civil Penalties
The bill imposes both criminal and civil penalties for individuals and companies that violate food safety laws:
For individuals who knowingly violate food safety laws, the measure allows for a prison term of up to 10 years.
For unintentional violations involving individuals, the measure imposes a fine of $20,000 per violation, not to exceed $50,000 in a single proceeding.
For unintentional violations involving companies, the bill imposes a fine of $250,000 per violation, not to exceed $1 million in a single proceeding.
For intentional violations with respect to individuals the fine would be $50,000 per violation, not to exceed $100,000 in a single proceeding.
For intentional violations involving companies, the fine would be $500,000 per violation, not to exceed $7.5 million in a single proceeding.

Annual Registration & Fees
The bill imposes new registration and fee requirements on food processing facilities. Farms, grocery stores, and restaurants would be exempt from these requirements. Farms that process food would be exempt as long as that food is consumed on the farm or another farm owned by the same individual.

Registration The bill requires the annual registration for all food facilities, and gives the FDA the authority to assess annual registration fees of $500, adjusted for inflation. Currently, both domestic and foreign food facilities must register with the FDA, however periodic renewal is not required and the FDA does not have the authority to collect fees. The measure allows the FDA to suspend a registration for any violation of the bill's regulations that could result in serious adverse health consequences or death to humans or animals. The bill establishes an appeals process for these suspensions.

For food importers, the measure provides that the FDA would determine the registration fee for FY 2010, and the fee would be adjusted for inflation thereafter.

The measure requires the Health and Human Services Department to submit, by March 30 of each year, the number of registered facilities; the number of domestic facilities; the number of foreign facilities; the number of high-risk and low-risk facilities; and the number of such facilities that hold food.

Fees Under the bill, fees would be collected and made available for obligation only in the amounts provided in appropriations legislation. The collection of fees would thus be credited as an offset to discretionary spending. The spending of funds collected as fees to regulate food products would be classified as discretionary spending and could be used only to cover the FDA's administrative costs to regulate food products at any point in the future.

Hazard Analysis & Food Safety Plan
Hazard Analysis The bill requires food facility owners, operators or their agents to conduct an analysis to determine whether there are any hazards that are "reasonably likely" to occur in the absence of preventive controls that may affect the safety, wholesomeness, or sanitation of the food manufactured, processed, packed, transported, or held by the facility. These hazards include biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, filth, decomposition, parasites, allergens, and unapproved food and color additives — as well as hazards that were intentionally or unintentionally introduced, including by acts of terrorism.

The measure also requires food facilities to implement "preventive controls" to prevent, eliminate, or reduce to "acceptable levels" the occurrence of any hazards identified in the hazard analysis. In addition, facilities would be required to implement procedures to ensure that, if the preventive controls are not fully implemented or are not effective, that none of its products enters commerce. Preventive controls would include sanitation procedures and practices; supervisor and employee hygiene training; an allergen control program to minimize potential allergic reactions in humans; good manufacturing practices; verification procedures for suppliers and incoming ingredients, which may include on-site auditing of suppliers and testing of incoming ingredients.

Food Safety Plan The bill requires food facilities to implement a written food safety plan, which would include the following:
The hazard analysis and any reanalysis conducted;
A description of the facility's record-keeping procedures;
A description of the preventive controls being implemented;
A description of verification activities for the preventive controls, including validation, review of monitoring and corrective action records, and procedures for determining whether the preventive controls are effectively eliminating or reducing the occurrence of identified hazards or conditions;
A description of the facility's procedures for the recall of articles of food, whether voluntarily or when required;
A description of the facility's procedures for tracing the distribution history of articles of food, whether voluntarily or when required; and
A description of the facility's procedures to ensure a safe and secure supply chain for the

ingredients or components used in making the food manufactured, processed, packed, and transported.

The measure allows the FDA to exempt from these requirements facilities that only produce food for animals or the storage of packaged foods that are "not exposed to the environment." The FDA could also exempt facilities that store raw agricultural commodities for further distribution or processing. The bill also requires the FDA to consider the impact of any regulations required by these provisions on small businesses. In addition, it requires the FDA to provide guidance to assist small businesses in complying with these requirements.

Safety Standards for Raw Agricultural Commodities
The measure directs the FDA to establish science-based standards for the safe growing, harvesting, packing, sorting, transporting, and holding of raw agricultural commodities that are a fruit, vegetable, nut, or fungus — and for which the FDA has determined that such standards minimize the risk of serious adverse health consequences or death to humans or animals. Such standards could address manure use, water quality, employee hygiene, sanitation and animal control, and temperature controls. The bill directs the FDA to provide a "reasonable period of time for compliance, taking into account the needs of small businesses for additional time to comply." In addition, the FDA would be required to take into consideration the impact of these standards on small-scale and diversified farms, wildlife habitat, conservation practices, and organic production methods.

Access to Records
The bill requires owners of food facilities to provide — at the request of the Department of Health Human Services — all records relating to determining whether food is adulterated, misbranded, or otherwise in violation of the bill's requirements. Such records include those relating to the production, manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of food. Farms would be exempt from this requirement unless an article of food from the farm is the subject of an active FDA investigation of a food borne illness outbreak

Owners would be required to report to a food registry and use accredited laboratories recognized by HHS for analytical testing of an article of food. In addition, the measure requires owners to notify the FDA of the identity and location of an article of food that is believed to be adulterated or misbranded and maintain records with respect to infant formula for at least one year after the expiration of the shelf life. They would also be required to identify the country in which the final processing occurred. For unprocessed food, the measure requires the identification of the country of origin.

Born and raised in Delaware County, former 3-star Admiral Joe Sestak served in the Navy for 31 years and now serves as the Representative from the 7th District of Pennsylvania. He led a series of operational commands at sea, including Commander of an aircraft carrier battle group of 30 U.S. and allied ships with over 15,000 sailors and 100 aircraft that conducted operations in Afghanistan and Iraq. After 9/11, Joe was the first Director of "Deep Blue," the Navy's anti-terrorism unit that established strategic and operations policies for the "Global War on Terrorism." He served as President Clinton's Director for Defense Policy at the National Security Council in the White House, and holds a Ph.D. in Political Economy and Government from Harvard University. According to the office of the House Historian, Joe is the highest-ranking former military officer ever elected to the Congress.